Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-367]

RIN 1117-AB39

Schedules of Controlled Substances: Table of Excluded Nonnarcotic Products: Vicks® VapoInhaler®

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule adopts the interim final rule, with a correction to spelling of the manufacturer's name that was published in the *Federal Register* on October 27, 2015. The Drug Enforcement Administration is amending the table of Excluded Nonnarcotic Products to update the listing for Vicks® VapoInhaler®, containing 50 mg levmetamfetamine in a nasal decongestant inhaler, marketed by The Procter & Gamble Company. This over-the-counter, non-narcotic drug product is excluded from provisions of the Controlled Substances Act.

DATES: This final rule is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Barbara J. Boockholdt, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and they are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II.

The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c) and the current list of all scheduled substances is published at 21 CFR part 1308.

The CSA states that the Attorney General shall by regulation exclude any nonnarcotic drug which contains a controlled substance from the application of the CSA, if such drug may, under the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 301 *et*

seq., be lawfully sold over-the-counter without a prescription. 21 U.S.C. 811(g)(1). Such exclusions apply only to specific nonnarcotic drugs following suitable application to the DEA in accordance with 21 CFR 1308.21. The current table of Excluded Nonnarcotic Products is found in 21 CFR 1308.22. The authority to exclude such substances has been delegated to the Administrator of the DEA, 28 CFR 0.100, and redelegated to the Deputy Assistant Administrator of the Office of Diversion Control, section 7 of 28 CFR part 0, appendix to subpart R.

Background

This final rule adopts, with a change to the spelling of the manufacturer's name, the interim final rule, "Schedules of Controlled Substances: Table of Excluded Nonnarcotic Products: Vicks® VapoInhaler®" that was published in the *Federal Register* on October 27, 2015. 80 FR 65635. The correct spelling of the manufacturer's name is "The Procter & Gamble Company." The interim final rule contained a typographical error in which "Procter" was inadvertently spelled as "Proctor."

On February 9, 2012, pursuant to the application process of § 1308.21, the DEA received correspondence from The Procter & Gamble Company ("P&G") notifying the DEA that it had reduced the quantity of *l*-desoxyephedrine (levmetamfetamine) from 113 mg to 50 mg in their Vicks® Inhaler™ product which is currently excluded under § 1308.22. Levmetamfetamine is controlled in schedule II as an isomer of methamphetamine. 21 CFR 1308.12(d)(2). P&G requested that the DEA update the current exclusion for its Vicks® Inhaler™ and indicated it had acquired Richardson-Vicks, Inc. (including its subsidiary, the Vick Chemical Company). The company stated that the product name has been modified from Vicks® Inhaler™ to Vicks® VapoInhaler® and that the change included a corresponding National Drug Code (NDC) number

reassignment by the U.S. Food and Drug Administration. Furthermore, P&G stated that the nomenclature for the active ingredient/controlled substance had been changed from *l*-desoxyephedrine to levmetamfetamine. P&G indicated that nothing in the formulation change affects other aspects of the drug delivery system.

Based on the application and other information received, including the quantitative composition of the substance and labeling and packaging information, the DEA determined that this product may, under the FD&C Act, be lawfully sold over-the-counter without a prescription. 21 U.S.C. 811(g)(1). In addition, the Deputy Assistant Administrator of the Office of Diversion Control found that the active ingredient in this drug product (levmetamfetamine) is a schedule II controlled substance and is not a narcotic drug as defined by 21 U.S.C. 802(17). The Deputy Assistant Administrator of the Office of Diversion Control therefore found and concluded that this product continues to meet the criteria for exclusion from the CSA pursuant to 21 U.S.C. 811(g)(1).

The interim final rule provided an opportunity for interested persons to submit written comments on the rule on or before December 28, 2015. The DEA received one comment in response to the publication of the interim final rule which was a request from P&G for a correction to the spelling of their name. As noted above, the spelling has been corrected in this final rule.

This exclusion only applies to the finished drug product in the form of an inhaler (in the exact formulation detailed in the application for exclusion), which is lawfully sold over-the-counter without a prescription under the FD&C Act. The extraction or removal of the active ingredient (levmetamfetamine) from the inhaler shall negate this exclusion and result in the possession of a schedule II controlled substance.

Regulatory Analyses

Executive Orders 12866 and 13563

This regulation has been developed in accordance with the Executive Orders 12866, "Regulatory Planning and Review," section 1(b) and Executive Order 13563, "Improving Regulation and Regulatory Review." The DEA has determined that this rule is not "a significant regulatory action," and accordingly this rule has not been reviewed by the Office of Management and Budget. As discussed above, this product was previously exempted under a different company name. As discussed in the interim final rule, this action will not have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment. The DEA determined, as explained in the interim final rule, that public notice and comment were impracticable and contrary to the public interest. Consequently, the RFA does not apply. Although the RFA does not apply to this rulemaking, the DEA has reviewed the potential impacts of this final rule and determined that it will not have a significant economic impact on a substantial number of small entities. As discussed above and in the interim final rule, this product was

previously exempted under a different company name. The Deputy Assistant Administrator, in accordance with the Regulatory Flexibility Act, has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, "Civil Justice Reform," to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

This rule does not have tribal implications warranting the application of Executive Order 13175. This rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Unfunded Mandates Reform Act of 1995

As stated in the interim final rule, the DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.*, that this action would not result in any Federal mandate that may result "in the expenditure by

State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year * * *." Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of the UMRA.

Paperwork Reduction Act

As stated in the interim final rule, this rule does not impose a new collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

Accordingly, for the reasons stated above, the interim final rule that was published in the *Federal Register* on October 27, 2015 (80 FR 65635), is adopted as final with the following change:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

2. Amend § 1308.22, in the table, by removing the company name, "Proctor & Gamble Co., The" and adding in its place "Procter & Gamble Co., The".

Dated: February 2, 2016

Louis J. Milione,
Deputy Assistant Administrator, Office of Diversion Control.
[FR Doc. 2016-02403 Filed: 2/5/2016 8:45 am; Publication Date: 2/8/2016]